

110TH CONGRESS
1ST SESSION

S. 2311

To amend the Federal Food, Drug, and Cosmetic Act to provide for the amendment or repeal of monographs, to expand the Food and Drug Administration's authority to regulate drug advertising, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2007

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the amendment or repeal of monographs, to expand the Food and Drug Administration's authority to regulate drug advertising, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Non-Prescription Drug
5 Modernization Act of 2007”.

1 **SEC. 2. AMENDING OR REPEALING MONOGRAPHS.**

2 Subchapter E of chapter V of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
4 amended by adding at the end the following:

5 **“SEC. 568. AMENDING OR REPEALING MONOGRAPHS.**

6 “(a) GOOD CAUSE.—In applying section 553 of title
7 5, United States Code, to any amendment to or repeal
8 of a monograph established pursuant to section 330.10 of
9 title 21, Code of Federal Regulations (or any successor
10 regulation), good cause (as such term is used in sub-
11 sections (b) and (d) of such section 553) is deemed to
12 exist, and notice and public procedure are deemed to be
13 unnecessary (as such term is used in subsection (b) of
14 such section 553), for purposes of making such amend-
15 ment or repeal if—

16 “(1) there is a finding—

17 “(A) by the Secretary that the category of
18 drugs or the specific drug involved is associated
19 with a significant risk; or

20 “(B) by the Secretary, after holding a
21 meeting of an advisory committee of the Food
22 and Drug Administration to evaluate the cat-
23 egory of drugs or the specific drug involved,
24 that such category of drugs or specific drug
25 lacks evidence of effectiveness; and

1 “(2) such amendment or repeal is based, in
2 whole or in part, on such finding.

3 “(b) SUBSEQUENT COMMENT PERIOD.—After the
4 amendment or repeal of a monograph in accordance with
5 subsection (a), the Secretary may provide a period for
6 public comments on the amendment or repeal and may
7 make additional changes with respect to the monograph
8 to reflect comments received, if determined appropriate by
9 the Secretary.”.

10 **SEC. 3. EXPANSION OF FDA’S AUTHORITY TO REGULATE**
11 **DRUG ADVERTISING.**

12 (a) IN GENERAL.—The Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

14 (1) in section 303(g)(1), by striking “With re-
15 spect to” and all that follows through “section 351
16 of the Public Health Service Act,” and inserting
17 “With respect to a person who is a holder of an ap-
18 proved application under section 505 or under sec-
19 tion 351 of the Public Health Service Act, or a per-
20 son who is the manufacturer of a drug marketed
21 pursuant to a monograph established pursuant to
22 section 330.10 of title 21, Code of Federal Regula-
23 tions (or any successor regulation),”; and

24 (2) in section 502(n)—

1 (A) by striking the term “prescription
2 drug” each place such term appears and insert-
3 ing “drug”; and

4 (B) by striking “subject to section
5 503(b)(1)”.

6 (b) REGULATIONS.—The Commissioner of Food and
7 Drugs shall promulgate such revisions to the regulations
8 under section 502(n) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 352(n)) as may be necessary to carry
10 out the amendments made by subsection (a).

11 (c) TRANSITIONAL PROVISIONS.—

12 (1) FALSE OR MISLEADING ADVERTISE-
13 MENTS.—During the period beginning on the date of
14 the enactment of this Act and ending on the effec-
15 tive date of the regulations required by subsection
16 (b), a drug other than a prescription drug is deemed
17 to be misbranded under section 502(n) of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C.
19 352(n)) if any advertisement or other descriptive
20 printed matter issued or caused to be issued by the
21 manufacturer, packer, or distributor with respect to
22 that drug is false or misleading.

23 (2) DEFINITIONS.—The terms used in this sub-
24 section have the meanings applicable to those terms

1 in section 502(n) of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 352(n)).

3 **SEC. 4. IDENTIFICATION AND REPORT ON MONOGRAPHS.**

4 (a) IDENTIFICATION.—

5 (1) IN GENERAL.—The Commissioner of Food
6 and Drugs (in this section referred to as the “Com-
7 missioner”) shall identify each monograph estab-
8 lished pursuant to section 330.10 of title 21, Code
9 of Federal Regulations, that may require further re-
10 view to determine whether the monograph is in need
11 of amendment or repeal.

12 (2) PUBLIC COMMENTS.—To assist in the iden-
13 tification of such monographs, the Commissioner
14 shall give interested persons, including medical soci-
15 eties and other entities with expertise on drugs, an
16 opportunity to submit comments.

17 (b) REPORT.—Not later than 2 years after the date
18 of the enactment of this Act, the Commissioner shall sub-
19 mit a report to the Congress identifying any monographs
20 that, as determined by the Commissioner, may require fur-
21 ther review to determine whether such monographs are in
22 need of amendment or repeal. Such report shall include—

23 (1) an assessment of the resources necessary to
24 conduct such review and make such amendments or
25 repeals;

1 (2) a summary of the comments received under
2 subsection (a)(2); and

3 (3) a listing of the monographs that, as rec-
4 ommended in such comments, are in need of amend-
5 ment or repeal and the basis for such recommenda-
6 tions.

7 **SEC. 5. AUTHORIZATION OF APPROPRIATIONS.**

8 To carry out this Act and the amendments made by
9 this Act, there are authorized to be appropriated such
10 sums as may be necessary.

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